

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

Art Unit: 1647

WOLFE ET AL.

Examiner: J. Seharaseyon

APPLICATION NO: 10/035,420

FILED: OCTOBER 25, 2001

FOR: METHODS OF PROTEIN PURIFICATION RECOVERY

MS: General

Commissioner for Patents

PO Box 1450

Alexandria, VA 22313-1450

APPLICATION FOR PATENT TERM ADJUSTMENT-PRE-GRANT

Sir:

In accordance with 37 C.F.R. § 1.705(b), Applicant hereby applies for patent term adjustment under 35 U.S.C. § 154(b) of 29 days. This application is being filed before or with payment of the issue fee, as required by 37 C.F.R. § 1.705(b).

I. Fee

As required by 37 C.F.R. § 1.705(b)(1), this application is accompanied by a request to charge Deposit Account No. 19-0134 for \$ 200.00 to cover the required fee (as defined in 37 C.F.R. § 1.18(e)). Please charge any deficiencies or any additional fees due in response to this request to Deposit Account. 19-0134.

II. Statement of the Facts Involved

A. Correct Patent Term Adjustment

The Determination of Patent Term Adjustment was received by Applicant on October 29, 2008, indicating a patent term adjustment of 0 days.

Patentee has calculated a patent term adjustment of 29 days based on the following facts:

Case Law

In *Wyeth v. Dudas*, 2008 U.S. Dist. LEXIS 76063 (D.D.C. 2008), the District Court of the District of Columbia addressed the United States Patent and Trademark Office (USPTO)

interpretation of 35 U.S.C. § 154(b)(2). The Court granted summary judgment in favor of Wyeth, determining that the USPTO misconstrued the first sentence of 35 U.S.C. § 154(b)(2)(A), and as a result, improperly denied Wyeth a portion of patent term to which Wyeth was entitled under 35 U.S.C. § 154.

In the opinion, the Court stated that "the PTO's view is that any administrative delay under § 154(b)(1)(A) overlaps any 3-year maximum pendency delay under § 154(b)(1)(B): the applicant gets credit for 'A delay' or for 'B delay,' whichever is larger, but never A + B." However, Plaintiff Wyeth argued that the § 154(b)(1)(A) and § 154(b)(1)(B) period overlap only if they occur on the same calendar day or days. The Court determined that Wyeth's construction of § 154(b)(2)(A) was correct.

Simply put, the holding of the Court is that the excluded overlap recited in the first sentence of 35 U.S.C. § 154(b)(2)(A) only occurs if a 35 U.S.C. § 154(b)(1)(A) period and a 35 U.S.C. § 154(b)(1)(B) period run concurrently. As such, a patent holder is entitled to recoup the 35 U.S.C. § 154(b)(1)(A) period that falls outside of the 35 U.S.C. § 154(b)(1)(B) period in addition to the 35 U.S.C. § 154(b)(1)(B) period itself.

Patent term adjustment is thus calculated by adding all PTO delay under 35 U.S.C. §§ 154(b)(1)(A)-154(b)(1)(B), subtracting all overlap therebetween under 35 U.S.C. § 154(b)(2)(A), subtracting applicant delay under 35 U.S.C. § 154(b)(2)(C), and subtracting any terminally disclaimed portion of the adjustment under 35 U.S.C. § 154(b)(2)(B).

Relevant Dates

The above-identified application has a 35 U.S.C. §371 filing date of October 25, 2001.

The first Office Action, which was a Restriction Requirement, was mailed on October 21, 2003 resulting in a PTO delay of 300 days beyond the 14 months provided by 35 U.S.C. §154(b).

A Response to Restriction was received from Applicants by the PTO on November 24, 2003.

A Non-final Rejection was mailed February 20, 2004.

A Response was received from Applicants by the PTO on August 17, 2004, resulting in an applicant delay of 89 days.

A Non-final Rejection was mailed November 8, 2004.

A Response was received from Applicants by the PTO on April 8, 2005, resulting in an applicant delay of 59 days.

A Final Rejection was mailed June 27, 2005.

A Notice of Appeal was received from Applicants by the PTO on November 30, 2005, resulting in an applicant delay of 64 days.

A Request for Continued Examination was received from Applicants by the PTO on February 2, 2006.

A Non-Final Rejection was mailed April 13, 2006.

A Response was received from Applicants by the PTO on September 13, 2006, resulting in an applicant delay of 62 days.

A Final Rejection was mailed November 27, 2006.

A Notice of Appeal was received from Applicants by the PTO on May 31, 2007, resulting in an applicant delay of 93 days.

A Request for Continued Examination and Amendment was received from Applicants by the PTO on December 10, 2007.

A Non-Final Rejection was mailed February 15, 2008.

An Amendment was received from Applicants by the PTO on July 15, 2008, resulting in an applicant delay of 61 days.

A Notice of Allowance was mailed October 29, 2008.

Accordingly, the total PTO adjustment based on delay under 35 U.S.C. § 154(b)(1)(A) is 300 days. The reduction in term adjustment due to applicant delay is 428 days under 35 U.S.C. § 154(b)(2)(C).

The 35 U.S.C. § 154(b)(1)(B) period for the above-identified application began on October 25, 2004 (three years after the filing date of October 25, 2001) and ended on February 2, 2006 (the filing date of an RCE). Accordingly, the 35 U.S.C. § 154(b)(1)(B) period is 465 days.

Within the 35 U.S.C. § 154(b)(1)(B) period (i.e., from December 12, 2006 to February 7, 2008), there is no 35 U.S.C. § 154(b)(1)(A) delay that should be excluded from the patent term adjustment calculation under the holding of *Wyeth v. Dudas*, as these two periods of delay do not overlap. There is thus no excluded delay under 35 U.S.C. § 154(b)(2)(A).

Aside from any terminal disclaimer, patent term adjustment of 337 days is calculated as the sum of the 35 U.S.C. § 154(b)(1)(B) (465 days) and non-overlapping 35 U.S.C. § 154(b)(1)(A) delay (300 days), minus 35 U.S.C. §(b)(2)(C) applicant delay (428 days) $((465 + 300 - 428 \text{ days}) = 337 \text{ days})$.

The above-identified application is subject to a Terminal Disclaimer over U.S. Patent No. 6,887,462, U.S. Patent No. 7,371,737 and U.S. Patent No. 7,399,463. The earliest expiration of these three patents is November 23, 2021 for U.S. Patent No. 6,887,462 (standard term expiration of October 25, 2021 + 29 days of patent term adjustment). The expiration date of a patent issuing from the above-identified patent application without patent term adjustment is October 25, 2021. In view of the terminal disclaimer, the calculated patent term adjustment of 337 days is reduced under 35 U.S.C. § 154(b)(2)(B) to 29 days.

The Patent Term Adjustment printed on the front of Notice of Patent Term Adjustment is only 0 days, which the USPTO is presumed to have calculated using the method considered proper before the holding of *Wyeth v. Dudas*. Applicants therefore respectfully request reconsideration of the Patent Term Adjustment, which, under the holding of *Wyeth v. Dudas*, should be 29 days.

B. Reasonable Efforts

Any applicant delays under 37 C.F.R. §1.704 are set forth above. There were no other circumstances constituting a failure to engage in reasonable efforts to conclude processing of examination of the above-identified application, as set forth in 37 C.F.R. §1.704.

Please charge the \$200 fee required by 37 C.F.R. §1.18(e) and any other fees that may be required to Deposit Account No. 19-0134 in the name of Novartis Corporation.

Respectfully submitted,

Novartis Pharmaceuticals Corp.
Patents Pharma
One Health Plaza, Building 101
East Hanover, NJ 07936-1080
(862) 778-9273

/Cozette M. McAvoy/
Cozette M. McAvoy
Attorney for Applicants
Reg. No. 60,457

Date: January 29, 2009